

68467-1A

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07/31/2014



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
Washington, D.C. 20460

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S 951657 | 1300

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

JUL 31 2014

Ms. Heidi Reistad  
Dow AgroSciences LLC  
9330 Zionsville Road  
Indianapolis, IN 46268-1054

Subject: WideStrike® x COT102  
EPA Reg. No: 68467-19  
Application for Notification Dated: May 1, 2014

Dear: Ms. Reistad:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under 98-10 dated above. A preliminary screen of this request (to establish WideStrike® 3 as the primary brand name and change WideStrike® x COT102 to become an alternate brand name) has been conducted for its applicability under PRN 98-10 and it has been determined that the action(s) requested falls within the scope of PRN 98-10. Our records have been duly noted, and the label submitted with this application has been stamped "Notification Accepted" and will be placed accordingly in our records.

Questions concerning this action should be directed to Denise Greenway at 703 308-8263 or email at greenway.denise@epa.gov.

Sincerely,

Kimberly Nesci, Chief  
Microbial Pesticides Branch  
Biopesticides and Pollution Prevention Division 7511P

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SYMBOL	▶	7511P	7511P				
SURNAME	▶	Greenway	Nesci				
DATE	▶	7/31/14	7/31/14				

2/16

# WideStrike® 3 Insect Resistant Cotton Seed

## Alternate Brand Name: WideStrike® x COT102

Pure form of the plant-incorporated protectant, *Bacillus thuringiensis* var. *aizawai* strain PS811 and *Bacillus thuringiensis* var. *kurstaki* strain HD73 delta endotoxin proteins and *Bacillus thuringiensis* strain AB88 VIP3Aa19 as produced in cotton cells. For control of Cotton Bollworm, Tobacco Budworm, Pink Bollworm, Beet Armyworm, Fall Armyworm, Southern Armyworm, Soybean Looper, Cabbage Looper, Black Cutworm, Citrus Peelminer, Cotton Leafperforator, European Corn Borer, Omnivorous Leafroller, and Saltmarsh Caterpillar.

**Active Ingredients:**

*Bacillus thuringiensis* var. *aizawai* Cry1F and the genetic material (from the insert of plasmid pGMA281) (event 281-24-36) necessary for its production in cotton (OECD Unique Identifier DAS-24236-5)  
1.24 – 2.19 ng/mg\*

*Bacillus thuringiensis* var. *kurstaki* Cry1Ac and the genetic material (from the insert of plasmid pMYC3006) (event 3006-210-23) necessary for its production in cotton (OECD Unique Identifier DAS-21023-5)  
0.41 – 0.76 ng/mg\*

*Bacillus thuringiensis* strain AB88 VIP3Aa19 and the genetic material (from plasmid pCOT1) (event COT102) necessary for its production in cotton (OECD Unique Identifier SYN-IR102-7)  
3.16 – 5.99 ng/mg \*

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\*ng/mg seed tissue on a dry weight basis

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

EPA REG. NUMBER: 68467-19

EPA ESTABLISHMENT NUMBER: 62719-IN-1

Mycogen Seeds  
c/o Dow AgroSciences LLC  
9330 Zionsville Road  
Indianapolis IN 46268

**Notification Accepted**

**Date:** JUL 31 2014

**Reviewer:** D. Greenway

3/16

## DIRECTIONS FOR USE

It is a violation of federal law to use this product in any manner inconsistent with its labeling.

The plant-incorporated protectant product is to be used as specified in the terms of the registration.

Cotton has been transformed to express *Bacillus thuringiensis* var. *aizawai* strain PS811, *Bacillus thuringiensis* var. *kurstaki* strain HD73 and *Bacillus thuringiensis* strain AB88 protein and the genetic material necessary for its production to control: Cotton Bollworm, Tobacco Budworm, Pink Bollworm, Beet Armyworm, Fall Armyworm, Southern Armyworm, Soybean Looper, Cabbage Looper, Black Cutworm, Citrus Peelminer, Cotton Leafperforator, European Corn Borer, Omnivorous Leafroller, and Saltmarsh Caterpillar.

The following information regarding commercial production must be included in the grower guide for WideStrike® 3 cotton:

- a) No planting of WideStrike® 3 cotton is permitted south of Route 60 (near Tampa) in Florida.
- b) Commercial culture of WideStrike® 3 cotton is prohibited in Hawaii, Puerto Rico, and the US Virgin Islands.

The following information regarding test plots and seed production must occur on bags of WideStrike® 3 cotton intended for the following purposes:

- a) Test plots or breeding nurseries, regardless of the plot size, established in Hawaii must not be planted within 3 miles of *Gossypium tomentosum*.
- b) Experimental plots and breeding nurseries of *Bt* cotton are prohibited on the U.S. Virgin Islands, and
- c) Test plots or breeding nurseries, regardless of the plot size, established on the island of Puerto Rico must not be planted within 3 miles of feral cotton plants.

Growers of WideStrike® 3 cotton in the states of Arizona, California, and New Mexico and in the following Texas counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler must employ one of the following structured refuge options:

### 1) External, Unsprayed Refuge:

Ensure that at least 5 acres of non-*Bt* cotton (refuge cotton) are planted for every 95 acres of WideStrike® 3 cotton (total of 100 acres). The size of the refuge must be at least 150 feet wide, but preferably 300 feet wide. This refuge may not be treated with sterile insects, pheromone, or any insecticide (except listed below) labeled for the control of tobacco budworm, cotton bollworm or pink bollworm. At the pre-squaring cotton stage only, the refuge may be treated with any lepidopteran insecticide to control foliage feeding caterpillars. At the pre-squaring cotton stage only, the refuge may be treated with acephate or methyl parathion at rates which will not control tobacco budworm or the cotton bollworm (equal to or less than 0.5 lb of active ingredient per acre). The variety of cotton planted in the refuge must be comparable to WideStrike® 3 cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, terminations, and management of other pests) similarly to WideStrike® 3 cotton. Ensure that a non-*Bt* cotton refuge is maintained within at least 1/2 linear mile (preferably adjacent to or within 1/4 mile or closer) from the WideStrike® 3 cotton fields.

## 2) External Sprayed Refuge

Ensure that at least 20 acres of non-*Bt* cotton (refuge cotton) are planted for every 80 acres of WideStrike® 3 cotton (total of 100 acres). The variety of cotton planted in the refuge must be comparable to WideStrike® 3 cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, terminations, and management of other pests) similarly to WideStrike® 3 cotton. The non-*Bt* cotton may be treated with sterile insects, insecticides (excluding foliar *Bt* products), or pheromones labeled for control of the tobacco budworm, cotton bollworm, or pink bollworm. Ensure that a non-*Bt* refuge is maintained within at least 1 linear mile (preferably within 1/2 mile or closer) from the WideStrike® 3 cotton fields

## 3) Embedded Refuge

Plant the refuge cotton as at least one single non-*Bt* cotton row for every six to ten rows of WideStrike® 3 cotton. The refuge may be treated with sterile insects, any insecticide (excluding foliar *Bt* products), or pheromone labeled for the control of pink bollworm whenever the entire field is treated. The in-field refuge rows may not be treated independently of the surrounding *Bt* cotton field in which it is embedded. The refuge must be managed (fertilizer, weed control, etc.) identically to the WideStrike® 3 cotton. There is no field unit option

## USE PATTERN

CROP	PESTS
cotton	Cotton Bollworm Tobacco Budworm Pink Bollworm Beet Armyworm Fall Armyworm Southern Armyworm Soybean Looper Cabbage Looper Black Cutworm Citrus Peelminer Cotton Leafperforator European Corn Borer Omnivorous Leafroller Saltmarsh Caterpillar

EPA Accepted: 04 / 11 / 2013



U.S. ENVIRONMENTAL PROTECTION AGENCY  
 Office of Pesticide Programs  
 Biopesticides and Pollution Prevention Division (7511P)  
 1200 Pennsylvania Avenue NW  
 Washington, D.C. 20460

**NOTICE OF PESTICIDE:**

Registration  
 Reregistration (under FIFRA, as amended)

EPA Reg. Number: 68467-19  
 Date of Issuance: APR 11 2013

Term of Issuance:  
**Unconditional**

Name of Pesticide Product:  
**WideStrike® x COT102**

Name and Address of Registrant (include ZIP Code):

Dow AgroSciences LLC  
 9330 Zionsville Road  
 Indianapolis, IN 46268

**Note:** Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

The registration application referred to above, submitted in connection with registration under § 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you comply with the following terms.

1. Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Change the EPA Registration Number entry to "EPA Reg. Number: 68467-19" on the final printed label.

Signature of Approving Official:  
 Keith A. Matthews, Director  
 Biopesticides and Pollution Prevention Division (7511P)

Date:  
 11 April 2013

EPA Form 8570-6

CONCURRENCES

SYMBOL	7511P	7511P	7511P	2011P			
SURNAME	Greenway	Reynolds	Neu	Matthews			
DATE	4/10/2013	4/10/13	4/11/13	11 Apr 2013			

EPA Form 1320-1A (1/90)

w/ear  
 on pg assumed +  
 (see handwritten Alan)

Printed on Recycled Paper

OFFICIAL FILE COPY

The following terms apply:

**Gene Flow**

The following information regarding commercial production must be included in the grower guide for WideStrike® x COT102 and is a term of this amendment:

- a) No planting of WideStrike® x COT102 is permitted south of Route 60 (near Tampa) in Florida.
- b) Commercial culture of WideStrike® x COT102 is prohibited in Hawaii, Puerto Rico, and the US Virgin Islands.

The following information regarding test plots and seed production must occur on bags of WideStrike® x COT102 intended for these purposes and is a term of this amendment.

- a) Test plots or breeding nurseries, regardless of the plot size, established in Hawaii must not be planted within 3 miles of *Gossypium tomentosum*.
- b) Experimental plots and breeding nurseries of *Bt* cotton are prohibited on the U.S. Virgin Islands, and
- c) Test plots or breeding nurseries, regardless of the plot size, established on the island of Puerto Rico must not be planted within 3 miles of feral cotton plants.

Upon approval by EPA, test plots and/or breeding nurseries in Hawaii, the U.S. Virgin Islands, and Puerto Rico may be established without restrictions if alternative measures, such as insecticide applications, are shown to effectively mitigate gene flow.

**Insect Resistance Management**

The required IRM program for WideStrike® x COT102 *Bt* cotton must have the following elements:

- Requirements relating to creation of a non-*Bt* cotton refuge in conjunction with the planting of any acreage of WideStrike® x COT102 *Bt* cotton in the states of Arizona, California, and New Mexico and in the following Texas counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler;
- Requirements for Dow AgroSciences LLC to prepare and require WideStrike® x COT102 *Bt* cotton users to sign “grower agreements” which impose binding contractual obligations on the grower to comply with the refuge requirements;
- Requirements for Dow AgroSciences LLC to develop, implement, and report to EPA on programs to educate growers about IRM requirements;
- Requirements for Dow AgroSciences LLC to develop, implement, and report to EPA on programs to evaluate and promote growers’ compliance with IRM requirements in the states of Arizona, California, and New Mexico and in the following Texas counties:

Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler;

- Requirements for Dow AgroSciences LLC to develop, implement, and report to EPA on programs to evaluate whether there are statistically significant and biologically relevant changes in susceptibility to the Cry1Ac, Cry1F and VIP3Aa19 proteins in the target insects;
- Requirements for Dow AgroSciences LLC to develop, and if triggered, to implement a “remedial action plan” which would contain measures Dow AgroSciences LLC would take in the event that any insect resistance was detected as well as to report on activity under the plan to EPA;
- Annual reports on or before January 31<sup>st</sup> each year, except as indicated in the sections below.

a. Refuge Requirements for Pink Bollworm Resistance Management only in the states of Arizona, California, and New Mexico and in the following Texas counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler

All growers of WideStrike® x COT102 must employ one of the following structured refuge options:

1) External, Unsprayed Refuge

Ensure that at least 5 acres of non-*Bt* cotton (refuge cotton) are planted for every 95 acres of WideStrike® x COT102 (total of 100 acres). The size of the refuge must be at least 150 feet wide, but preferably 300 feet wide. This refuge may not be treated with sterile insects, pheromone, or any insecticide (except listed below) labeled for the control of tobacco budworm, cotton bollworm, or pink bollworm. At the pre-squaring cotton stage only, the refuge may be treated with any lepidopteran insecticide to control foliage feeding caterpillars. At the pre-squaring cotton stage only, the refuge may be treated with acephate or methyl parathion at rates which will not control tobacco budworm or the cotton bollworm (equal to or less than 0.5 lb of active ingredient per acre). The variety of cotton planted in the refuge must be comparable to WideStrike® x COT102, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, terminations, and management of other pests) similarly to WideStrike® x COT102. Ensure that a non-*Bt* cotton refuge is maintained within at least ½ linear mile (preferably adjacent to or within 1/4 mile or closer) from the WideStrike® x COT102 fields.

2) External Sprayed Refuge

Ensure that at least 20 acres of non-*Bt* cotton (refuge cotton) are planted for every 80 acres of WideStrike® x COT102 (total of 100 acres). The variety of cotton planted in the refuge must be comparable to WideStrike® x COT102 especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, terminations, and management of other pests) similarly to WideStrike® x COT102. The non-*Bt* cotton may be treated with sterile insects, insecticides (excluding foliar *Bt* products), or pheromones labeled for control of the tobacco budworm, cotton bollworm, or pink

bollworm. Ensure that a non-*Bt* refuge is maintained within at least 1 linear mile (preferably within ½ mile or closer) from the WideStrike® x COT102 cotton fields.

### 3) Embedded Refuge

Plant the refuge cotton as at least one single non-*Bt* cotton row for every six to ten rows of WideStrike® x COT102. The refuge may be treated with sterile insects, any insecticide (excluding foliar *Bt* products), or pheromone labeled for the control of pink bollworm whenever the entire field is treated. The in-field refuge rows may not be treated independently of the surrounding *Bt* cotton field in which it is embedded. The refuge must be managed (fertilizer, weed control, etc.) identically to the WideStrike® x COT102 cotton. There is no field unit option.

b. Natural Refuge Requirements for Tobacco Budworm and Cotton Bollworm Resistance Management only in the states of Alabama, Arkansas, Florida, Georgia, Kansas, Kentucky, Louisiana, Maryland, Missouri, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas (excluding the following counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler), and Virginia (natural refuge refers to weeds, wild hosts or other cultivated crops that serve as sources of susceptible insects to mitigate any potential resistant insects arising from the *Bt* crops).

- 1) Dow AgroSciences LLC must submit data to EPA by January 31<sup>st</sup>, 2017, and every five years thereafter, to support an EPA reassessment of the natural refuge and to confirm its effectiveness with tobacco budworm and cotton bollworm. The data must include: resistance monitoring data, cropping pattern analysis, and simulation modeling to reexamine levels of effective refuge in the states of Alabama, Arkansas, Florida, Georgia, Kansas, Kentucky, Louisiana, Maryland, Missouri, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, and Virginia. Both cropping and land use patterns can change over time, which could impact the amount of natural refuge available to tobacco budworm and cotton bollworm relative to cotton. If based on this reassessment, EPA determines that additional tobacco budworm and/or cotton bollworm sampling, gossypol analysis, statistical analysis, and simulation modeling are needed to justify continuation of the natural refuge, Dow AgroSciences LLC must submit these data within the EPA requested timeframe. If EPA's assessment concludes that the natural refuge is no longer scientifically supported, Dow AgroSciences LLC agrees to submit an application to amend the registration to restore the structured refuge requirements previously required for tobacco budworm and cotton bollworm uses.
- 2) It is recommended that Dow AgroSciences LLC develop a more complex, spatial model of resistance for WideStrike® x COT102 cotton that further considers the evolution of resistance "hotspots" (i.e. localized areas of resistance) and provide EPA with this information. Key issues like spatial structure, linkage disequilibrium, and differential movement of males and females have not yet been explored in detail for pyramided *Bt* proteins. Such models would be more desirable to examine the resistance evolution at the local level where natural refuge may be limited for one or more generations of tobacco budworm.

c. Grower Agreements

While Dow AgroSciences LLC will have flexibility to design its program to fit its own business practices, Dow AgroSciences LLC must meet the following requirements.

- 1) Persons purchasing the WideStrike® x COT102 cotton product must sign a grower agreement. The term “grower agreement” refers to any grower purchase contract, license agreement, or similar legal document.
- 2) The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.
- 3) Dow AgroSciences LLC must continue to implement a system which is reasonably likely to assure that persons purchasing the WideStrike® x COT102 cotton product will affirm annually that they are contractually bound to comply with the requirements of the IRM program.
- 4) Dow AgroSciences LLC must continue to use an approved grower agreement. If Dow AgroSciences LLC wishes to change any part of the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty days prior to implementing a proposed change, Dow AgroSciences LLC must submit to EPA the text of such changes to ensure the agreement is consistent with the terms of this registration.
- 5) Dow AgroSciences LLC must continue an approved system which is reasonably likely to assure that persons purchasing the WideStrike® x COT102 cotton sign grower agreement(s).
- 6) Dow AgroSciences LLC shall maintain records of all WideStrike® x COT102 cotton grower agreements for a period of three years from December 31 of the year in which the agreement was signed.
- 7) Dow AgroSciences LLC must maintain records detailing the number of units of the WideStrike® x COT102 cotton seed shipped and not returned and the number of such units that were sold to persons who have signed grower agreements. Dow AgroSciences LLC must submit the records to EPA upon request.
- 8) Dow AgroSciences LLC must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that the names, personal information, and grower license number will be kept as confidential business information.

d. IRM Education and IRM Compliance Monitoring Programs

Dow AgroSciences LLC must implement the following IRM education and compliance monitoring programs:

- 1) Dow AgroSciences LLC must design and implement a comprehensive, ongoing IRM education program designed to convey to WideStrike® x COT102 cotton users the importance of complying with the IRM program. The program shall include information encouraging WideStrike® x COT102 cotton users to pursue optional elements of the IRM program relating to refuge configuration and proximity to WideStrike® x COT102 cotton fields. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, and electronic communications such as by internet or television commercials. Copies of the materials, including the Grower Guide or other technical bulletins, must be submitted to EPA for their records. The program shall involve at least one written communication annually to each WideStrike® x COT102 cotton grower separate from the grower agreement. Dow AgroSciences LLC shall coordinate its education program with educational efforts of other organizations, such as the National Cotton Council and state extension programs.
- 2) Annually, Dow AgroSciences LLC shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraph 6 and from other sources. The changes shall address aspects of grower compliance that are not sufficient.
- 3) Beginning January 31, 2014 and annually thereafter, Dow AgroSciences LLC shall provide a report to EPA summarizing the activities it carried out under its education program for the prior year and its plans for its education program during the current year.
- 4) Dow AgroSciences LLC shall continue to implement an ongoing IRM compliance assurance program in the states of Arizona, California, and New Mexico and in the following Texas counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler. The program is designed to evaluate the extent to which growers are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to the *Bt* cotton product. Other required features of the program are described in paragraphs 5 - 12 below.
- 5) Dow AgroSciences LLC shall establish and publicize a "phased compliance approach," i.e., a guidance document that indicates how Dow AgroSciences LLC will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers. The options shall include withdrawal of the right to purchase WideStrike® x COT102 cotton for an individual grower or for all growers in a specific region. An individual grower found to be significantly out of compliance two years in a row would be denied sales of the product the next year.

- 6) The IRM compliance assurance program shall include an annual survey of a statistically representative sample of WideStrike® x COT102 cotton growers conducted by an independent third party. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. Dow AgroSciences LLC shall provide a written summary of the results of the prior year's survey to EPA by January 31st of each year. Dow AgroSciences LLC shall confer with EPA on the design and content of the survey prior to its implementation.
- 7) Annually, Dow AgroSciences LLC shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey required under paragraph 6] and from other sources. The changes shall address aspects of grower compliance that are not sufficient. Dow AgroSciences LLC will confer with the Agency prior to adopting any changes.
- 8) Dow AgroSciences LLC must conduct an annual on-farm assessment program. Dow AgroSciences LLC shall train its representatives who make on-farm visits with WideStrike® x COT102 cotton growers to perform assessments of compliance with IRM requirements. In the event that any of these visits results in the identification of a grower who is not in compliance with the IRM program, Dow AgroSciences LLC shall take appropriate action, consistent with its "phased compliance approach," to promote compliance.
- 9) Dow AgroSciences LLC shall carry out a program for investigating "tips and complaints" that an individual grower or growers is/are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, Dow AgroSciences LLC shall take appropriate action, consistent with its "phased compliance approach."
- 10) If a grower, who purchases WideStrike® x COT102 cotton for planting, was specifically identified as not being in compliance during the previous year, Dow AgroSciences LLC shall visit the grower and evaluate whether the grower is in compliance with the IRM program for the current year.
- 11) By January 31, 2010 and annually thereafter, Dow AgroSciences LLC shall provide a report to EPA summarizing the activities it carried out under its compliance assurance program for the prior year and its plans for its compliance assurance program during the current year. Included in that report will be the percent of growers using each refuge option (or combination of options) by region, the approximate number or percent of growers visited on farm by Dow AgroSciences LLC, and the results of these visits, the number of tips investigated, the percent of growers not in compliance with each refuge option (both size and distance), and the follow-up actions taken.
- 12) Dow AgroSciences LLC must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that the names, personal information, and grower license number of the growers will be kept as confidential business information.

e. Insect Resistance Monitoring.

Dow AgroSciences LLC must carry out appropriate programs to detect the emergence of insect resistance as early as possible. Resistance monitoring programs include: surveying insects for potential resistance and collection of information from growers about events that may indicate resistance. Dow AgroSciences LLC should coordinate its monitoring efforts for WideStrike® x COT102 with the current resistance monitoring programs for other registered *Bt* cotton products. For WideStrike® x COT102 cotton, the Agency imposes the following:

- 1) Dow AgroSciences LLC must continue to develop and ensure the implementation of a plan for resistance monitoring for *Heliothis virescens* (tobacco budworm), *Helicoverpa zea* (cotton bollworm), and *Pectinophora gossypiella* (pink bollworm). The plan shall include provision for conducting annual studies to evaluate any potential change in susceptibility of tobacco budworm, cotton bollworm and pink bollworm populations to Cry1Ac, Cry1F and VIP3Aa19 proteins. Collection sites must be focused in areas of high adoption, with the goal of including all states where these insects are economic pests.
- 2) The following testing scheme for survivors of the diagnostic or discriminating concentrations (or identified survivors of any resistance detection method) must be implemented: 1) Determine if the observed effect is heritable; 2) Determine if the increased tolerance can be observed in the field (i.e., survive on WideStrike® x COT102 cotton plants); 3) Determine if the effect is due to resistance, 4) Determine the nature of resistance (dominant, recessive), 5) Determine the resistance allele frequency, 6) Determine, in subsequent years, whether the resistance allele frequency is increasing, and 7) Determine the geographic extent of the resistance allele (or alleles) distribution. Should the resistance allele frequency be increasing and spreading, a specific remedial action plan should be designed to mitigate the extent of *Bt* resistance. See section f. ("Remedial Action Plans") below.
- 3) Dow AgroSciences LLC must also follow up on grower, extension specialist or consultant reports of less than expected results or control failures (such as increases in damaged squares or bolls) for the target lepidopteran pests (*Heliothis virescens* (TBW) and *Helicoverpa zea* (CBW), *Pectinophora gossypiella* (PBW)) as well as for cabbage looper, soybean looper, saltmarsh caterpillar, black cutworm, fall armyworm, southern armyworm, and European corn borer. Dow AgroSciences LLC will instruct its customers (growers and seed distributors) to contact them (e.g., via a toll-free customer service number) if incidents of unexpected levels of tobacco budworm, cotton bollworm, or pink bollworm damage occur. Dow AgroSciences LLC will investigate all damage reports. See Remedial Action Plans section below.
- 4) Dow AgroSciences LLC must provide to EPA for review and approval any revisions to the tobacco budworm, cotton bollworm, and pink bollworm resistance monitoring plans prior to their implementation.
- 5) A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by June 30th each year for tobacco budworm and cotton bollworm and by December 31<sup>st</sup> each year for pink bollworm.

f. Remedial Action Plans

Specific remedial action plans are required for WideStrike® x COT102 cotton for the purpose of containing resistance and perhaps eliminating resistance if it develops. One remedial action plan is for the area where pink bollworm is the predominate pest and the other is for the area where tobacco budworm and cotton bollworm are the predominate pests.

1) Remedial Action Plan for Pink Bollworm

If resistance involves the pink bollworm (*Pectinophora gossypiella*), Dow AgroSciences LLC must implement the Arizona *Bt* Cotton Working Group's Remedial Action Plan. Dow AgroSciences LLC must obtain approval from EPA before modifying the Arizona *Bt* Cotton Working Group's Remedial Action Strategy. The Arizona *Bt* Cotton Working Group's Remedial Action Plan can be found in Enclosure 1.

2) Remedial Action Plan for Tobacco Budworm and Cotton Bollworm

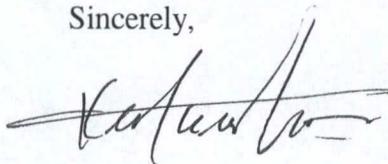
If resistance involves the tobacco budworm (*Heliothis virescens*) and/or the cotton bollworm (*Helicoverpa zea*), Dow AgroSciences LLC must implement a Remedial Action Plan approved by EPA. Dow AgroSciences LLC must obtain approval from EPA before modifying the Remedial Action Plan for Cotton Bollworm and Tobacco Budworm.

**Annual Reports**

Dow AgroSciences LLC will provide an annual report to EPA on its Cry1Ac, Cry1F and VIP3Aa19 plant-incorporated protectants (PIPs) expressed in cotton. This report must include, but is not limited to, grower education completed last year and planned for the following year with any changes highlighted, the description of grower agreements in place, grower compliance with IRM requirements including compliance with the community refuge option, and insect resistance monitoring results.

A stamped copy of the label is enclosed for your records.

Sincerely,



Keith A. Matthews  
Director  
Biopesticides and Pollution  
Prevention Division (7511P)

Enclosures (2)

DGreenway/308-8263/4.4.2013/68467-RO reg not widestrike x cot102.doc

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## WideStrike® x COT102 Insect Resistant Cotton Seed

Pure form of the plant-incorporated protectant, *Bacillus thuringiensis* var. *aizawai* strain PS811 and *Bacillus thuringiensis* var. *kurstaki* strain HD73 delta endotoxin proteins and *Bacillus thuringiensis* strain AB88 VIP3Aa19 as produced in cotton cells. For control of Cotton Bollworm, Tobacco Budworm, Pink Bollworm, Beet Armyworm, Fall Armyworm, Southern Armyworm, Soybean Looper, Cabbage Looper, Black Cutworm, Citrus Peelminer, Cotton Leafperforator, European Corn Borer, Omnivorous Leafroller, and Saltmarsh Caterpillar.

### Active Ingredients:

*Bacillus thuringiensis* var. *aizawai* Cry1F and the genetic material (from the insert of plasmid pGMA281) (event 281-24-36) necessary for its production in cotton (OECD Unique Identifier DAS-24236-5)  
1.24 – 2.19 ng/mg\*

*Bacillus thuringiensis* var. *kurstaki* Cry1Ac and the genetic material (from the insert of plasmid pMYC3006) (event 3006-210-23) necessary for its production in cotton (OECD Unique Identifier DAS-21023-5)  
0.41 – 0.76 ng/mg\*

*Bacillus thuringiensis* strain AB88 VIP3Aa19 and the genetic material (from plasmid pCOT1) (event COT102) necessary for its production in cotton (OECD Unique Identifier SYN-IR102-7)  
3.16 – 5.99 ng/mg \*

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\*ng/mg seed tissue on a dry weight basis

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

EPA REG. NUMBER: 68467-xx

EPA ESTABLISHMENT NUMBER: 62719-IN-1

Mycogen Seeds  
c/o Dow AgroSciences LLC  
9330 Zionsville Road  
Indianapolis IN 46268

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**ACCEPTED**

APR 11 2013

Under the Federal Insecticide, Fungicide,  
and Rodenticide Act, as amended, for  
the pesticide registered under  
EPA Reg. No.

68467-19

## DIRECTIONS FOR USE

It is a violation of federal law to use this product in any manner inconsistent with its labeling.

The plant-incorporated protectant product is to be used as specified in the terms of the registration.

Cotton has been transformed to express *Bacillus thuringiensis* var. *aizawai* strain PS811, *Bacillus thuringiensis* var. *kurstaki* strain HD73 and *Bacillus thuringiensis* strain AB88 protein and the genetic material necessary for its production to control: Cotton Bollworm, Tobacco Budworm, Pink Bollworm, Beet Armyworm, Fall Armyworm, Southern Armyworm, Soybean Looper, Cabbage Looper, Black Cutworm, Citrus Peelminer, Cotton Leafperforator, European Corn Borer, Omnivorous Leafroller, and Saltmarsh Caterpillar.

The following information regarding commercial production must be included in the grower guide for WideStrike® x COT102 cotton:

- a) No planting of WideStrike® x COT102 cotton is permitted south of Route 60 (near Tampa) in Florida.
- b) Commercial culture of WideStrike® x COT102 cotton is prohibited in Hawaii, Puerto Rico, and the US Virgin Islands.

The following information regarding test plots and seed production must occur on bags of WideStrike® x COT102 cotton intended for the following purposes:

- a) Test plots or breeding nurseries, regardless of the plot size, established in Hawaii must not be planted within 3 miles of *Gossypium tomentosum*.
- b) Experimental plots and breeding nurseries of *Bt* cotton are prohibited on the U.S. Virgin Islands, and
- c) Test plots or breeding nurseries, regardless of the plot size, established on the island of Puerto Rico must not be planted within 3 miles of feral cotton plants.

Growers of WideStrike® x COT102 cotton in the states of Arizona, California, and New Mexico and in the following Texas counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler must employ one of the following structured refuge options:

### 1) External, Unsprayed Refuge:

Ensure that at least 5 acres of non-*Bt* cotton (refuge cotton) are planted for every 95 acres of WideStrike® x COT102 cotton (total of 100 acres). The size of the refuge must be at least 150 feet wide, but preferably 300 feet wide. This refuge may not be treated with sterile insects, pheromone, or any insecticide (except listed below) labeled for the control of tobacco budworm, cotton bollworm or pink bollworm. At the pre-squaring cotton stage only, the refuge may be treated with any lepidopteran insecticide to control foliage feeding caterpillars. At the pre-squaring cotton stage only, the refuge may be treated with acephate or methyl parathion at rates which will not control tobacco budworm or the cotton bollworm (equal to or less than 0.5 lb of active ingredient per acre). The variety of cotton planted in the refuge must be comparable to WideStrike® x COT102 cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, terminations, and management of other pests) similarly to WideStrike® x COT102 cotton. Ensure that a non-*Bt* cotton refuge is maintained within at least 1/2 linear mile (preferably adjacent to or within 1/4 mile or closer) from the WideStrike® x COT102 cotton fields.

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2) External Sprayed Refuge

Ensure that at least 20 acres of non-*Bt* cotton (refuge cotton) are planted for every 80 acres of WideStrike® x COT102 cotton (total of 100 acres). The variety of cotton planted in the refuge must be comparable to WideStrike® x COT102 cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, terminations, and management of other pests) similarly to WideStrike® x COT102 cotton. The non-*Bt* cotton may be treated with sterile insects, insecticides (excluding foliar *Bt* products), or pheromones labeled for control of the tobacco budworm, cotton bollworm, or pink bollworm. Ensure that a non-*Bt* refuge is maintained within at least 1 linear mile (preferably within 1/2 mile or closer) from the WideStrike® x COT102 cotton fields

3) Embedded Refuge

Plant the refuge cotton as at least one single non-*Bt* cotton row for every six to ten rows of WideStrike® x COT102 cotton. The refuge may be treated with sterile insects, any insecticide (excluding foliar *Bt* products), or pheromone labeled for the control of pink bollworm whenever the entire field is treated. The in-field refuge rows may not be treated independently of the surrounding *Bt* cotton field in which it is embedded. The refuge must be managed (fertilizer, weed control, etc.) identically to the WideStrike® x COT102 cotton. There is no field unit option

**USE PATTERN**

CROP	PESTS
cotton	Cotton Bollworm Tobacco Budworm Pink Bollworm Beet Armyworm Fall Armyworm Southern Armyworm Soybean Looper Cabbage Looper Black Cutworm Citrus Peelminer Cotton Leafperforator European Corn Borer Omnivorous Leafroller Saltmarsh Caterpillar

EPA Accepted: \_\_\_\_/\_\_\_\_/\_\_\_\_